

510 (k) Summary
(As Required By 21 CFR 807.92(a))

Date Prepared

January 10, 2013

Submitter's Information

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OCT 08 2013

Establishment Registration for Elliquence, LLC is 3007024186.

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Trade Name

Device Trade Name is Meddusa Bipolar System

Device Common, Usual, or Classification Names

Electrosurgical Cutting and Coagulation Device and Accessories.

Classification Panel

Classification of this device would fall under the responsibility of the Division of General, Restorative, and Neurological Devices.

Class

Classification: Class 2.

Product Code: GEI, 21 CFR 878.4400

Predicate Device

- Bipolar Trigger-Flex Probe (510(k) K003126)
- Aquamantys 2.3 Bipolar Sealer (510(k) K052859)
- Disc-FX System (510(k) K052241)

Description of the Device

The Meddusa Bipolar System is a disposable device manufacturer of medical grade Stainless Steel, ABS plastic and TEFLON heat shrink tubing. The category of contact as classified by ISO 10993-1:2003 are that the device is an (1) External Communicating Device, (2) Contact Area: Tissue, Bone, Dentin, (3) Contact Duration <24 hrs.

The Meddusa Bipolar System is classified as Sterile, Surgically Invasive, Active Device, with intended patient contact for a period for <1hr (Transient).

The Meddusa Bipolar System is intended to be used with the elliquence Surgi-Max / Surgi-Max Plus Radiofrequency generator (510(k) K100390). The Surgi-Max emits high frequency, low-temperature radiowaves which is directed to the Meddusa Bipolar System tip. The electrical power operating at radio frequency (RF) is transferred to tissue at the surgical site. The time-varying voltage produced by the electrical power source yields a predetermined electrosurgical effect, such as tissue cutting or coagulation.

Intended Use

The Meddusa Bipolar System is a single-use product designed for and intended to be used exclusively with Surgi-Max® RF Generators (510(k) K100390). For optimal performance the Surgi-Max® Plus generator (510(k) K100390) is recommended.

The Meddusa™ Bipolar System is intended for use by a physician familiar with bipolar coagulation with electrosurgery where coagulation/contraction of soft tissue is needed. The types of surgery intended are: General surgery, Laparoscopic procedures, Endoscopic procedures, Laryngeal coagulation, Open abdominal, Orthopedic coagulation, Thorascopic coagulation, Neurosurgical coagulation, Gynecological coagulation, (except for use in female sterilization), Ear, Nose, Throat coagulation.

Technological Characteristics

The device is substantially equivalent to the predicate device based on a comparison on physical and performance characteristics.

Performance Data

The subject device is composed of biocompatible materials, has passed dielectric testing, and performs similarly to the predicate devices. Bench tests used ex vivo tissue that included liver, kidney, and muscle tissue. The subject device and predicate devices were compared to demonstrate the thermal effect on tissue by measuring the width and depth of the thermally damaged zones in relation to tissue type, intensity setting, and duration of activation. The temperature profile of the subject device applicator and cable was recorded during simulation use for the maximum energy delivery duration at the maximum power to demonstrate the maximum applicator surface area and maximum cable surface temperature will be safe to the user and/or to the patient. The peak temperatures of the electrode tips and target tissue/vessels when the device is used for the maximum recommended duration and generator output settings was compared. Based on the results of the various bench tests, it was determined that the subject device is safe and effective.

Conclusion

We conclude that the subject device is safe and effective as the predicate device.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

Elliquence Innovative Medical Solutions
Mr. John Pikramenos
Product Development Director
2455 Grand Avenue
Baldwin, New York 11510

October 8, 2013

Re: K130110

Trade/Device Name: Meddusa Bipolar System
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: GE1
Dated: September 13, 2013
Received: September 17, 2013

Dear Mr. Pikramenos:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Mark N. Melkerson -S

Mark N. Melkerson
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use


510(k) Number (if known): K130110

Device Name: Meddusa Bipolar System.

Indications For Use:

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Prescription Use 
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE
IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Long H.
Chen -A

Digitally signed by Long H. Chen -A
DN: cn=US, o=U.S. Government, ou=HHS,
ou=FDA, ou=People, cn=Long H. Chen -A
0.9.2342.19200300.100.1.1=1300369056
Date: 2013.10.08 12:41:56 -0400

for MXM

(Division Sign-off)
Division of Surgical Devices
510(k) Number K130110